



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

December 9, 2005

FILE COPY

David L. Rosen, B.S., Pharm., J.D.
Foley & Lardner, LLP
Washington Harbour
3000 K Street, N.W., Suite 500
Washington, DC 20007-5143

Dear Mr. Rosen:

Your petition requesting the Food and Drug Administration to stay action regarding the proposed amendment to the monograph for Cough, Cold, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use was received by this office on 12/8/2005. It was assigned docket number 1976N-0052G/PSA 1 and it was filed on 12/8/2005. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe
Division of Dockets Management
Office of Management Programs
Office of Management

1976N-0052G

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